Application No. 10/517,686
Paper Dated December 9, 2007
In Reply to USPTO Correspondence of August 9, 2007
Attorney Docket No. 0470-045923

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claims 1-17 (Cancelled)

Claim 18 (Currently Amended): A method of treating or preventing prophylactically treating an immune mediated disorder in a mammal, said immune mediated disorder being selected from the group consisting of multiple sclerosis; autoimmune diseases; rheumatoid arthritis; and osteoarthritis; insulin dependent diabetes (type I diabetes); systemic lupus erythrematosis; psoriasis; immune pathologies induced by infectious agents, viral infections or bacterial infections; tuberculosis, lepromatous leprosy; transplant rejection; graft versus host disease; atopic conditions; eosinophilia; conjunctivitis and glomerular nephritis, and said method comprising the administration of a therapeutically effective amount of an estrogenic component selected from the group consisting of; substances represented by the following formula

$$R_7$$
 R_6
 R_5
 R_2
 R_3
 R_4

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$$R_7$$
 R_6
 R_1
 R_2
 R_3
 R_4

in which formula R_1 , R_2 , R_3 , R_4 independently are a hydrogen atom, a hydroxyl group or an alkoxy group with 1-5 carbon atoms; each of R_5 , R_6 , R_7 is a hydroxyl group; no more than 3 of R_1 , R_2 , R_3 , R_4 are hydrogen atoms;

precursors capable of liberating a substance according to the aforementioned formula when used in the present method, which precursors are derivatives of the estrogenic substances wherein the hydrogen atom of at least one of the hydroxyl groups has been substituted by an acyl radical of a hydrocarbon carboxylic, sulfonic acid or sulfamic acid of 1-25 carbon atoms; tetrahydrofuranyl; tetrahydropyranal; or a straight or branched chain glycosydic residue containing 1-20 glycosidic units per residue; and

mixtures of one or more of the aforementioned substances and/or precursors.

Claim 19 (Previously Presented): The method according to claim 18, wherein R₃ represents a hydroxyl group or an alkoxy group.

Claim 20 (Previously Presented): The method according to claim 18, wherein at least 3 of the groups R₁, R₂, R₃, and R₄ represent hydrogen atoms.

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Claim 21 (Previously Presented): The method according to claim 18, wherein

the estrogenic component exhibits an 8β, 9α, 13β, 14α configuration of the steroid-skeleton.

Claim 22 (Previously Presented): The method according to claim 18, wherein

the method comprises the uninterrupted administration of the estrogenic component during a

period of at least 5 days.

Claim 23 (Previously Presented): The method according to claim 18, wherein

the method comprises oral or subcutaneous administration of the estrogenic component.

Claim 24 (Previously Presented): The method according to claim 23, wherein

the method comprises oral administration.

Claim 25 (Previously Presented): The method according to claim 18, wherein

the estrogenic component is administered in an amount of at least 1 µg per kg of bodyweight per

day.

Claim 26 (Previously Presented): The method according to claim 18, wherein

the immune mediated disorder is a T-lymphocyte mediated disorder and/or a chronic

inflammatory disease.

Claim 27 (Previously Presented): The method according to claim 26, wherein

the immune mediated disorder is a Th1 mediated disorder.

Claim 28 (Previously Presented): The method according to claim 18, wherein

the immune mediated disorder is selected from the group consisting of multiple sclerosis,

rheumatoid arthritis, osteoarthritis, insulin dependent diabetes (type I diabetes), systemic lupus

erythrematosis and psoriasis.

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Claim 29 (Withdrawn): A pharmaceutical formulation comprising the estrogenic component as defined in claim 18, an immunotherapeutic agent and a pharmaceutically acceptable excipient.

Claim 30 (Withdrawn): The pharmaceutical formulation according to claim 29, wherein the formulation comprises at least 10 µg of the estrogenic component.

Claim 31 (Withdrawn): The pharmaceutical formulation according to claim 29, wherein the formulation comprises at least 1 µg of the immunotherapeutic agent.

Claim 32 (Withdrawn): The pharmaceutical formulation according to claim 29, wherein the immunotherapeutic agent is selected from the group consisting of antiinflammatory agents; D-pencillamine; 4-aminoquinoline agents; azathioprine; methotrexate;
cyclosporin; monoclonal antibodies to T lymphocytes, adhesion molecules ors to cytokines and
growth factors; Tumor Necrosis Factor Receptor (TNFR)-IgG; IL-1 receptor antagonists; ICE
inhibitors; betaferon; vitamin D; $1\alpha,25$ -dihydroxyvitamin D₃ and $1\alpha,25$ -dihydroxyvitamin D₂;
agents that specifically bind a molecule selected from the group consisting of a T cell receptor,
an antigen and a HLA molecule; organic gold derivatives such as a gold sodium thiomalate,
aurothioglucose, or auranofin and an angiogenesis inhibitor.

Claim 33 (Withdrawn): An oral unit dosage form comprising a pharmaceutical formulation according to claim 29.